

Remarks

Applicants respectfully submit the following remarks and amendments in response to the Office Action mailed April 12, 2007 ("Office Action"). Claims 15-16, 22-26 and 30-39 are pending, with claim 15 currently amended. Reconsideration and allowance of the claims is earnestly solicited.

Obviousness Rejections

In the Office Action, Claim 15, and those claims depending from claim 15, were rejected as allegedly being obvious under 35 U.S.C. §103(a) over US Patent 5,284,153 to Raymond et al. in view of US Patent 6,027,456 to Feler et al. Applicants respectfully traverse these rejections for the following reasons.

In order to advance prosecution on the merits, Applicants have amended independent claim 15 to define more particularly the subject matter sought to be patented, without prejudice to pursue the original subject matter, for example, in a continuation application.

Claim 15, as currently amended, is directed at a method for assessing the proximity of a spinal nerve relative to a probe or surgical tool being introduced towards the lumbar or thoracic regions of a patient's spine. Applicants amended the preamble to further clarify that the spinal nerve of interest in the present invention exits from the spinal canal and is disposed generally parallel to a longitudinal axis of the spine along the lateral aspect (the importance of this clarification will be explained in greater detail below). The method comprises the steps of:

- (a) emitting a stimulus signal from an electrode disposed on a probe or surgical tool as said probe or tool is introduced towards a lateral aspect of at least one of a vertebral body and an intervertebral disc of at least one of a lumbar region and thoracic region of a patient's spine;
- (b) electromyographically monitoring muscles coupled to said spinal nerve to determine if a predetermined neuro-muscular response is elicited by the stimulus signal;
- (c) increasing the intensity level of said stimulus signal until said predetermined neuro-muscular response is elicited by said stimulus pulse and stopping the emission of said stimulus signal immediately after said predetermined neuro-muscular response is detected; and
- (d) communicating to an operator said intensity level of said stimulus signal required to elicit said predetermined neuro-muscular response, wherein said intensity level required to elicit said predetermined neuro-muscular response represents the proximity of said spinal nerve to said probe or surgical tool.

At the outset, Applicants would like to thank the Examiner for the acknowledgement that none of the cited references teach a lateral approach to the spine, and that the amendments to the preamble make claim 15 more definite. To add to this clarity, claim 15 has been further amended to clearly reflect that the spinal nerve of interest exits from the spinal canal and extends generally parallel to the longitudinal axis of the spine along the lateral aspect thereof.

This is an important distinction in that the “nerve proximity detection” feature of the present invention allows a surgeon to detect the proximity of the spinal nerves disposed along the lateral aspect of the spine in order to safely and reproducibly reach the lumbar or thoracic region

of the spine via a lateral approach. The lateral surgical approach to the spine has distinct advantages over traditional approaches, such as the traditional anterior and posterior surgical approaches. The anterior approach to the lumbar spine, for example, requires extremely careful and delicate manipulation and/or retraction of the great vessels extending longitudinally along the anterior aspect of the lumbar spine in order to advance a probe or surgical tool to the anterior aspect of the spine. The posterior approach to the spine avoids the vascular challenges of the anterior approach, but is closer to the spinal chord itself and oftentimes requires the extremely careful and delicate removal of bone structures in the dorsal column of the spine in order to reach the vertebral bodies and/or intervertebral discs.

The lateral approach to the spine (as set forth in amended claim 15) overcomes these challenges. More specifically, the lateral approach to the spine avoids the need to traverse close to the great vessels located along the anterior aspect of the spine (as in the anterior approach) as well as the need to traverse close to the spinal chord and/or remove boney elements in the dorsal column (as in the posterior approach). The challenge with the lateral approach, however, is that the exiting nerve roots extend longitudinally along the lateral aspect of the lumbar and thoracic regions of the spine. Without the “nerve proximity” feature of the present invention, a surgeon would be loath to attempt to approach the spine using the lateral approach for fear of impinging upon and possibly damaging the existing spinal nerves disposed along the lateral aspect of the ventral column. By recognizing this threat, and the previously unmet need, the Applicants invented the present method, whereby safe and reproducible access may be gained to the lumbar and thoracic regions of the spine via a lateral approach.

Claim 15 has also been amended to reflect that the emission of the stimulus signal is immediately stopped after the predetermined neuro-muscular response is detected. This is a safety mechanism designed to remove the stimulation of the spinal nerve during the processing time required to communicate the intensity level to a user (e.g. surgeon or other operating room personnel) and during the time required for the user to make a determination of the proximity of the spinal nerve to the probe or surgical tool based on the communicated intensity level (e.g. not close – free to continue towards lateral aspect; relatively close – use caution when proceeding towards lateral aspect; too close – do not proceed towards lateral aspect).

This avoids the unnecessary stimulation found, for example, in the Raymond '153 reference. More specifically, as evident in Col 3, lines 28-32, Raymond '153 teaches that "The amount of current generated by the electrical source is automatically controlled so as to maintain the signal generated as a function of the response of the nerve to the stimuli." This is further evidenced at Col. 3, lines 47-52 which states, "As the response to the detecting device begins to detect a response to the stimuli, and as the needle is inserted deeper within the tissue in the direction of the nerve to be located, the current intensity is automatically decreased as the needle approaches the nerve." This does not stop the stimulation altogether, as found in claim 15, and thus subjects the nerve to unnecessary stimulation that may result in irritation and/or damage over time. The present invention eliminates any such drawback by stopping the stimulation immediately after the predetermined neuro-muscular response is detected.

Based on the foregoing distinctions between claim 15 and the prior art of record, Applicants respectfully submit that one of ordinary skill in the art would not have been led to the

present invention (as now claimed) based on the cited references. Claim 15 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 16, 22-26 and 30-39, being dependant upon and further limiting independent claim 15, should be allowed for the reasons set forth in support of the allowability of claim 15, as well as the additional limitations they contain.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Conclusion

Favorable consideration and allowance of the claims are respectfully requested. In the event that there are any questions concerning this Response to Office Action or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,
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